

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Stomp et al.
Application Serial No.: 10/677,441
Filed: October 2, 2003
For: *Genetically Engineered Duckweed*

Confirmation No.: 9042
Group No.: 1638
Examiner: Li Zheng

Date: November 19, 2007

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Commissioner for Patents
P.O. Box 1450
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**TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION-37 C.F.R. § 41.37)**

1. Transmitted herewith is the APPEAL BRIEF for the above-identified application, pursuant to the Notice of Appeal filed on August 28, 2007.

2. This application is filed on behalf of
☐ a small entity.

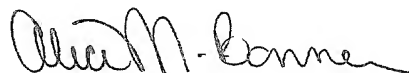
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Respectfully submitted,

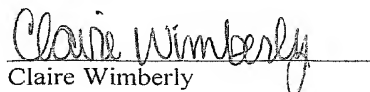


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Claire Wimberly

Attorney Docket No.: 5051-337DVCT3

PATENT

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APPELLANT'S BRIEF ON APPEAL UNDER 37 C.F.R. § 41.37

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed August 28, 2007. Enclosed herewith is a Petition for Extension of Time for one month. The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of **\$630.00** (\$510.00 as the fee for filing an Appeal Brief and \$120.00 as the fee for a one-month extension of time). This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any refund to Deposit Account No. 50-0220.

REAL PARTY IN INTEREST

The real party in interest is North Carolina State University (NCSU), the assignee of the rights to this application by virtue of assignment from the inventors to NCSU, recorded at the United States Patent and Trademark Office on October 26, 1998 on Reel 009548, Frame 0262.

RELATED APPEALS AND INTERFERENCES

Appellants are aware of no related appeals or interferences that would be affected by the present appeal.

STATUS OF CLAIMS

Claims 1-40 are pending in the present application as of the filing date of this Appeal Brief. As of the filing date of this Appeal Brief, claims 1-40 stand finally rejected on the ground of non-statutory double patenting as noted in the Final Office Action mailed February 28, 2007 and the Advisory Action mailed September 18, 2007.

Appellants appeal the rejection of claims 1-40. A copy of claims 1--40 is attached hereto as **Claims Appendix**, presenting the claims at issue as twice rejected in the Final Office Action dated February 28, 2007.

STATUS OF AMENDMENTS

All amendments made by Appellants during prosecution are believed to be entered as indicated by the Final Office Action dated February 28, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is drawn to stably transformed duckweed cells, tissues, plants and seed, wherein the transformed tissues can be used, for example, as a plant based gene expression system. Specification, page 3, lines 23-24; and page 6, lines 17-18.

Accordingly, independent **claim 1** is directed to a stably transformed duckweed plant comprising a heterologous nucleic acid of interest incorporated in its genome. Specification, page 3, lines 23-24; page 6, lines 20-32. The term duckweed refers to members of the family *Lemnaceae*, which has four genera and 34 species of duckweed. Specification, page 7, line 25 through page 8, line 2.

Any nucleic acid of interest can be used; for example, a duckweed plant can be stably transformed to express disease and insect resistance genes, genes conferring nutritional value, antifungal, antibacterial or antiviral genes, and the like. Alternatively, therapeutic (*e.g.*, for veterinary or medical uses) or immunogenic (*e.g.*, for vaccination) peptides and proteins can be expressed using transformed duckweed according to the present invention. Specification, page 8, lines 6-13.

The nucleic acid of interest can also be a nucleic acid for controlling gene expression. For example, the nucleic acid to be transferred can encode an antisense oligonucleotide. Alternately, duckweed can be transformed with one or more genes to reproduce enzymatic

pathways for chemical synthesis (*e.g.*, for the synthesis of plastics) or other industrial processes (*e.g.*, keratinase). In some embodiments, the nucleic acid encodes a secreted protein or peptide or a mammalian regulatory protein. In other embodiments, the duckweed can be engineered to produce biologically active multimeric proteins. Specification, page 8, line 14 through page 9, line 16.

Independent **claim 13** is directed to a stably transformed duckweed plant tissue comprising a heterologous nucleic acid of interest incorporated in its genome. Thus, in this case the stably transformed duckweed is plant tissue. Specification, page 3, lines 23-24; and page 16, lines 8-30.

Independent **claim 19** is directed to a stably transformed duckweed cell comprising a heterologous nucleic acid of interest incorporated in its genome. Accordingly, the stably transformed duckweed is a duckweed cell. Specification, page 3, lines 23-24; and page 16, lines 8-10.

Independent **claim 20** is directed to a stably transformed duckweed plant comprising a chimeric nucleic acid of interest incorporated in its genome, wherein said chimeric nucleic acid comprises a coding sequence operably linked to a transcription initiation region that is heterologous to said coding sequence. Specification, page 10, lines 22-24.

Independent **claim 34** is directed to a stably transformed duckweed plant tissue comprising a chimeric nucleic acid of interest incorporated in its genome, wherein said chimeric nucleic acid comprises a coding sequence operably linked to a transcription initiation region that is heterologous to said coding sequence. Thus, in this case the stably transformed duckweed is plant tissue. Specification, page 3, lines 23-24; and page 16, lines 8-30.

Independent **claim 40** is directed to a stably transformed duckweed cell comprising a chimeric nucleic acid of interest incorporated in its genome, wherein said chimeric nucleic acid comprises a coding sequence operably linked to a transcription initiation region that is heterologous to said coding sequence. Accordingly, the stably transformed duckweed is a duckweed cell. Specification, page 3, lines 23-24; and page 16, lines 8-10.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-10, 12-31 and 33-40 are properly rejected as unpatentable on the ground of non-statutory obviousness-type double patenting over claims 1 and 22-25 of U.S. Patent No. 6,815,184 (assigned to Biolex, Inc.)

2. Whether claims 11 and 32 are properly rejected as unpatentable on the ground of non-statutory obviousness-type double patenting over claim 1 of U.S. Patent No. 6,815,184 (assigned to Biolex, Inc.) in view of Dieryck et al. (*Transfus. Clin. Biol.* 2: 441-447 (1995)).

3. Whether claims 1-10, 12-31 and 33-40 are properly rejected as unpatentable on the ground of non-statutory obviousness-type double patenting over claims 1 and 22-25 of U.S. Patent Application No. 11/778,480 (assigned to Biolex, Inc.).

4. Whether claims 11 and 32 are properly rejected as unpatentable on the ground of non-statutory obviousness-type double patenting over claim 1 of U.S. Patent No. 6,815,184 (assigned to Biolex, Inc.) in view of Dieryck et al. (*Transfus. Clin. Biol.* 2: 441-447 (1995)).

ARGUMENT

I. Claims 1-10, 12-31 and 33-40 are improperly rejected as unpatentable on the ground of non-statutory obviousness-type double patenting over claims 1 and 22-25 of U.S. Patent No. 6,815,184.

The Final Office Action mailed February 2, 2007 (hereinafter the "Final Action") and the Advisory Action mailed September 18, 2007 (hereinafter the "Advisory Action") have maintained the rejection of claims 1-10, 12-31 and 33-40 as unpatentable on the ground of non-statutory obviousness-type double patenting over claims 1 and 22-25 of U.S. Patent No. 6,815,184 (hereinafter "the '184 patent").

As noted in Appellants' response to the Final Office Action dated August 28, 2007 (hereinafter "the August 28, 2007 Response") the '184 patent has only 17 claims. Thus, the '184 patent has no claims 22-25. As further noted in the August 28 Response, Appellants' representatives confirmed with the Examiner that claims 1 and 17 of the '184 patent were intended to be referred to in this double patenting rejection and not claims 22-25.

Accordingly, in the following discussion, Appellants will refer to claims 1 and 17 of the '184 patent.

The Purposes for a Double Patenting Rejection to Prevent the Unjustified Timewise Extension of the Right to Exclude Granted by a Patent and to Prevent Harassment by Multiple Parties Do Not Apply to the Present Case

Appellants respectfully submit that the present double patenting rejection is improper. As an initial point, Appellants would like to point out that the present application and the '184 patent are owned and have always been owned by two separate entities. The Appellants' application is the earlier filed of the two by nearly four years. Thus, there would be no timewise extension of patent term as the present application, if granted, would expire years before the '184 patent.

MPEP Section 804 indicates that:

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity of the term of the patent. The public policy behind this doctrine is that:

The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent, but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.

MPEP (Rev. 5, Aug. 2006), Section 804, page 800-11.

As further noted in the discussion that follows, "double patenting exists when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982)." *Id.* As pointed out above, in the present case, the extension of patent term is not an issue. The present application has an effective filing date of August 12, 1997 and if issued into a patent would expire August 13, 2017, well before the expiration date of the '184 patent.

The prohibition against the unjust extension of patent term is further reiterated in Section 804 of the MPEP, page 800-21, which sets forth that a nonstatutory double patenting rejection "is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887,

225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

The present application has an effective filing date that is earlier than the filing date of the '184 patent. The priority date for the present application is August 12, 1997, whereas the priority date for the '184 patent is July 31, 2000. Based on the filing dates, the issuance of a patent in the present case will not extend patent term. In fact, a patent issuing from the present application will expire before the '184 patent. Accordingly, there is no patent term extension.

In response to Appellants' argument in the August 28, 2007 Response that the present application will not have a term that extends beyond the term of the '184 patent, the Advisory Action mailed September 18, 2007 states that a further rationale for requiring a terminal disclaimer is the concern of possible harassment by multiple assignees. The United States Court of Customs and Appeals in *In re Van Ornum* confirmed that this was a further rationale for requiring a terminal disclaimer and the tying together of the ownership (non-alienation) of two patents (686 F.2d 937, 948, 214 U.S.P.Q. 761, 770 (CCPA 1982)).

Whenever the courts have discussed the concern of harassment by multiple assignees it has always been in terms of commonly owned patents that might subsequently be assigned or transferred to different parties. The court addressed this common ownership in *In re Van Ornum*, where it stated that "[t]his provision would prevent harassment of an alleged infringer by multiple parties due to subsequent different ownership of multiple patents granted as the result of filing a terminal disclaimer to overcome a double patenting rejection" (686 F.2d at 945, 214 U.S.P.Q. at 768; emphasis added). In *Chisom on Patents*, a discussion of the issue of harassment by multiple assignees states that "[e]ven though both patents are issued to the same patentee or assignee, it is possible that ownership of the two would be divided by later transfer and assignments" (*Chisom on Patents*, Donald S. Chisom, Chapter 9, section 9.04[2][b][ii]; emphasis added). Since a terminal disclaimer can only be filed where the patents or applications are commonly owned, the requirement that a terminal disclaimer include a non-alienation clause dictates that there is common ownership.

With regard to the '184 patent and the application at issue, these two inventions were never commonly owned and the inventors in each case were by law required to assign to different owners (employers). At no time were these two inventions commonly owned. Accordingly, Appellants respectfully submit that the issue of harassment by multiple assignees does not apply to this case.

There Is No Double Patenting Issue for the Present Application in View of the '184 Patent.

The section of the MPEP that governs the present situation is MPEP 804.03 IV, pages 800-37 through 800-39, regarding rejections under 35 USC § 102 and § 103 and double patenting. Form paragraph 7.21.01 *Provisional Rejection, 35 USC 103(a), Common Assignee or at Least One Common Inventor* should be applied to the present situation. The present application and the '184 patent do not have a common assignee or are not subject to a joint research agreement as defined by The CREATE Act. The present application and the '184 patent do share a common inventor.

MPEP form paragraph 7.21.01 indicates that in the present case the claims of the '184 patent should have been provisionally rejected under 35 USC § 103(a) as obvious over the present application, which was copending during the prosecution of the '184 patent. As stated in the form paragraph, "[b]ased upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. § 102(e) if published or patented. This provisional rejection under 35 U.S.C. § 103(a) is based upon a presumption of future publication or patenting of the conflicting application." MPEP, page 800-38.

As noted in the discussion that follows, this form paragraph should be used by an examiner to provisionally reject claims not patentably distinct from the disclosure in a copending application having an earlier U.S. filing date and also having either a common assignee or at least one common inventor. As noted on page 800-39, "if an application has a later effective U.S. filing date than a conflicting issued patent, the examiner should consider making a rejection in the application, based on the patent, under 35 U.S.C. § 102(e) or §§ 102(e)/103(a) using form paragraph 7.15.02 or 7.21.02." The discussion distinguishes the present situation from the situation where the application and the patent are subject to a joint research agreement under The CREATE Act.

The fact overlooked by the Examiner in the present application is the fact that the **present application has an effective filing date that is earlier** than the filing date of the '184 patent. The priority date for the present application is August 12, 1997, whereas the priority date for the '184 patent is July 31, 2000. Thus, the '184 patent is not prior art for purposes of double patenting under 35 U.S.C. § 102 or § 103. The present application is the earlier filed application. Further, the present product claims were filed with the originally filed U.S. application in 1998 (U.S. Patent Application No. 09/132536) and were pending at the time the application that matured into the '184 patent was under prosecution. Thus, the proper rejection that could have been made by the examiner was to reject the application that matured into the '184 patent application over the present application. Appellants note that the application that matured into the '184 patent was determined by the USPTO to be both novel and non-obvious over the prior art including the PCT counterpart of the present application (PCT/US98/16683; WO 99/07210), which was specifically considered during this patentability evaluation.

In conclusion, based upon the procedures set forth in the MPEP based upon current patent law there is no double patenting issue for the present application in view of the '184 patent. Accordingly, the double patenting rejection should be withdrawn.

The CREATE Act Safe-Harbor Provisions Do Not Apply to the Present Application

As noted above, the present application and the '184 patent are not commonly assigned, nor subject to a joint research agreement, as provided by The CREATE Act. Thus, the double patenting concerns brought about by the CREATE Act are not an issue in the present application. The CREATE Act provides a simple means of extending the "safe harbor" provisions of current law that treats inventions of a common owner similarly to inventions made by a single person. To promote collaborative research within organizations, Congress enacted the Patent Law Amendments of 1984, which, inter alia, exempt "common owner" inventors from the application of certain types of prior art and information in obviousness determinations, subject to the exercise of the same double patenting principles that apply when inventions are made by a single inventor. Importantly, "[p]atents issued under this Act shall be enforceable in the same manner, to the same extent, and for the same term as when patents are issued to a common owner or are subject to common assignment. The doctrine of 'obviousness-type double patenting,' a judicial doctrine used by courts to

prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent's right to exclude, shall apply to such patent." H.R. REP. 108-425, page 5.

As set forth in Department of Commerce RIN 0651-AB76:

Once an examiner has established a *prima facie* case of obviousness under 35 U.S.C. § 103(a), the burden is on the Appellant to overcome the rejection by invoking 35 U.S.C. § 103(c) as amended by the CREATE Act. . . To overcome such a rejection via the CREATE Act, the Appellant must provide a statement in compliance with § 1.104(c)(4) to the effect that the prior art and the claimed invention were made by or on the behalf of parties to a joint research agreement, within the meaning of 35 U.S.C. § 103(c)(3), which was in effect on or before the date the claimed invention was made, and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. . . If the Appellant disqualifies the subject matter relied upon by the examiner in accordance with the CREATE Act and the procedures set forth in this final rule, the examiner will treat the application under examination and the 35 U.S.C. § 102(e), (f), or (g) prior art as if they are commonly owned for purposes of 35 U.S.C. § 103.

Federal Register Vol. 70, No. 177, 54259, 54261.

Thus, parties who seek to benefit from the CREATE Act waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection. A double patenting rejection is authorized where an Appellant invokes the new provisions of 35 U.S.C. § 103(c), even though there is neither a common inventor nor a common patent owner. Rule 1.109(b).

As discussed in the MPEP and in the CREATE Act, double patenting rejections may arise as a result of the amendment to 35 U.S.C. § 103(c) by the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). Congress recognized that this amendment to 35 U.S.C. § 103(c) would result in situations in which there would be double patenting rejections between applications not owned by the same party (see, H.R. Rep No. 108-425, at 5,6 (2003)). For purposes of double patenting analysis, the application or patent and the subject matter disqualified under 35 U.S.C. § 103(c) as amended by the CREATE Act will be treated as if commonly owned.

Congress recognized that this amendment to 35 U.S.C. § 103 (c) would result in situations in which there would be double patenting between applications not owned by the same party. *See* H.R. Rep. No. 108-425, at 5-6 (2003). Therefore, the Office is providing the following guidelines for double patenting rejections based upon a patent or application that is not commonly owned but was disqualified under 35 U.S.C. § 103(c) as resulting from

activities undertaken within the scope of a joint research agreement, which will be incorporated into the next revision of the MPEP.

Federal Register Vol. 70, No. 177, 54259, 54261.

However, this new category of double patenting created by the CREATE Act does not apply to the present application. Appellants are not seeking to benefit from the provisions provided by the CREATE Act. Furthermore, Appellants cannot take advantage of the provisions of the CREATE Act since there was no joint research agreement in place between the assignee of the present application and the assignee of the '184 patent at the time of invention of the present application. Accordingly, double-patenting under the CREATE Act does not apply to the present application and the rejection should be withdrawn.

Appellants further note that the MPEP section addressing the requirements of a double patenting rejection states that an "[o]bviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a *commonly owned patent*, or a *non-commonly owned patent but subject to a joint research agreement* as set forth in 35 U.S.C. § 103(c)(2) and (3), when the issuance of a second patent would provide *unjustified extension of the term* of the right to exclude granted by a patent." MPEP § 804(II)(B)(1) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001) and *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000)) (emphasis added). The present application and the '184 patent are not commonly owned, nor are they subject to a joint research agreement. Further, there is no unjustified extension of term in this case (the term of protection for the present application will expire at least 3 years prior to that of the '184 patent). Thus, the fundamental purpose for which the judicially created doctrine of obviousness-type double patenting was intended, i.e., to prevent the unjustified extension of the term of the right to exclude granted by a patent (which purpose is repeated throughout the MPEP), is not present in this case (*See*, MPEP § 804, § 804 (II), § 804(II)(B) and § 804(II)(B)(1)).

Additionally, the MPEP states:

If the provisions of 35 U.S.C. 103(c)(1) apply to the commonly owned conflicting inventions of different inventive entities or if the provisions of 35 U.S.C. 103(c)(2) apply to non-commonly owned inventions subject to a joint research agreement and thereby obviate the obviousness rejection(s), double patenting rejection(s) should be made (or maintained) as appropriate. **If, however, it is determined that the provisions of 35 U.S.C. § 103(c) do NOT apply** because the inventions were not commonly owned or subject to

an obligation of assignment to the same person at the time the later invention was made, or because the claimed invention did NOT result from activities undertaken within the scope of a joint research agreement as required by 35 U.S.C. § 103(c)(2) and (3), **and** there is evidence of record to indicate that a patent or application is prior art against the application being examined, the examiner should make (A) any appropriate double patenting rejection(s), and (B) the appropriate prior art rejection(s) under 35 U.S.C. § 102 and/or 35 U.S.C. § 103 in the application being examined.

MPEP § 804.03(IV) (emphasis added). Again, none of these fact patterns identified as appropriate for a double patenting rejection are found in the instant case. The provisions of §103(c) do not apply and the '184 patent is not prior art against the present application.

The same scenarios that are discussed in MPEP § 804.03(IV) (discussed in the preceding paragraph) are presented in Chart IIB in § 804 of the MPEP (marked copy enclosed herewith in the Evidence Appendix). Chart IIB is a flow chart providing an outline of the treatment of applications with conflicting claims. If one follows the path for "different inventive entities, at least one common inventor and no common assignee" (middle of the chart) and then follows the path for "no joint research agreement" (all of which are the circumstances of the present application), this chart shows that a double patenting rejection is appropriate when the reference application or patent is prior art against the patent application at issue. It is specifically noted in Chart IIB that the term "**AND**" is used between the different rejections to be made. The use of "AND" is clearly intentional as "AND/OR" is used in another section of Chart IIB (see the path for "currently commonly owned→different inventive entities"). Thus, the drafters of this section of the MPEP clearly understood the difference and deliberately chose to use "AND" under the particular circumstances where the application and the application/patent have different inventive entities, at least one common inventor, no common assignee, and no joint research agreement. As stated previously, since the '184 patent does not qualify as prior art against the present application, these rejections as outlined in Chart IIB cannot be made. Thus, Appellants respectfully submit that the requirements for a proper double patenting rejection as set forth in the MPEP are not met in this case, and therefore, the present double patenting rejection is improper.

Even if a Double Patenting Rejection were Proper, the Appropriate Test is the Two-Way Obviousness Test.

Appellants submit that should a double patenting rejection be determined to be proper, then the appropriate test in the circumstances of the present application is a two-way obviousness test. In considering the issue of non-statutory obviousness-type double patenting the MPEP states that a "[i]f the patent is the later filed application, the question of whether the timewise extension of the right to exclude granted by a patent is justified or unjustified must be addressed. A two-way test is to be applied only when the applicant could not have filed the claims in a single application *and* there is administrative delay." MPEP, § 804(II)(B)(1)(b).

Furthermore, In *In re Bratt* (937 F.2d 589, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991)), the Court of Appeals for the Federal Circuit agreed with "...the proposition that when a later filed improvement patent issues before an earlier filed basic invention, a double patenting rejection is only proper against the claims to the basic invention if the improvement is not patentably distinct from the basic invention. The rationale behind this proposition is that an Appellant (or Appellants), who files applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the Appellant does not have complete control." (937 F.2d at 593, 19 U.S.P.Q.2d at 1292; emphasis added). In *In re Bratt*, the court found that not only could the claims of the later filed application not have been included in the earlier filed application but that the Appellant did not have complete control over the progress of the applications through the PTO. (937 F.2d at 593-4, 19 U.S.P.Q.2d at 1292).

In the present case, the improvement in the later filed application that matured into the '184 patent could not have been presented in the present application as the '184 application claims an invention not disclosed in the present application. (See, *In re Berg* 140 F.3d 1428, 1438; 46 U.S.P.Q.2d 1226, 1233 (1998)). Secondly, the second filed invention (that matured into the '184 patent) was not conceived until after the present application was filed (2001 and 1997, respectively). Lastly, the applications are owned a prosecuted by different assignees.

In addition, the Appellants did not have control over the rate of progress of both applications through the PTO. The Appellants have diligently prosecuted the family of applications from which the present application is derived. Appellants did not file the '184 application as it is owned by an entirely different entity. Thus, Appellants not only did not

have any control over when (or if) the second application was filed, they had no control over its prosecution.

It is unfair to penalize an entity with an earlier filed application by allowing a second file application of completely different entity to block the first filed application simply because the first entity employed an inventor who decided to pursue a career with the second entity and then invented improvements to the first entity's invention. This is clearly something that is out of the control of the first entity. The present case represents just this circumstance when an inventor leaves the auspices of a prior employer to be employed by another company, often a competitor. The only connection these inventions have is a single inventor. Thus, Appellants had no control over the filing and prosecution of the second filed application.

As it stands, the USPTO's position on the present double patenting rejection achieves absurd results. Since the application and patent at issue were filed as two separate inventions under the auspices of two separate entities, a terminal disclaimer cannot be filed to overcome the rejection. Thus, in this case, the senior party would appear to be blocked from obtaining a patent by a junior party. If this rejection is maintained, the only way to achieve any fairness is to apply the two way obviousness test. Accordingly, Appellants contend that if a double patenting rejection is found to be proper then the appropriate test for such a rejection is the two-way obviousness test.

Applying the two-way obviousness test requires application of the Graham obviousness analysis twice, once with the application claims as the claims in issue and once with the patent claims in issue. MPEP § 804(II)(B)(1)(b). If either analysis does not compel a conclusion of obviousness, no double patenting rejection of the obvious type is made. *Id.* Appellants note that the '184 patent was determined by the USPTO to be both novel and non-obvious over the prior art including the PCT counterpart of the present application (PCT/US98/16683; WO 99/07210), which was specifically considered during the patentability evaluation of the '184 patent. Thus, at least one of the required analyses under the two-way obviousness test does not compel a conclusion of obviousness and therefore, the double patenting rejection cannot be made.

For all of these reasons, the rejections of claims 1-10, 12-31 and 33-40 on the ground of non-statutory obviousness-type double patenting over claims 1 and 22-25 of U.S. Patent No. 6,815,184 should be reversed.

II. Claims 11 and 32 are improperly rejected as unpatentable on the ground of non-statutory obviousness-type double patenting over claim 1 of U.S. Patent No. 6,815,184 in view of Dieryck et al. (Transfus. Clin. Biol. 2: 441-447 (1995)).

The Final Action further maintains the obviousness-type double patenting rejection against claims 11 and 32 over claim 1 of U.S. Patent No. 6,815,184 in view of Dieryck et al. Appellants submit that this rejection is improper for the same reasons as set forth above, but for purposes of complying with the requirements under 37 CFR 41.37 (c)(viii) that each ground of rejection must be treated under a separate heading, all of the same arguments are **repeated** below.

The Purposes for a Double Patenting Rejection to Prevent the Unjustified Timewise Extension of the Right to Exclude Granted by a Patent and to Prevent Harassment by Multiple Parties Do Not Apply to the Present Case

Appellants respectfully submit that the present double patenting rejection is improper. As an initial point, Appellants would like to point out that the present application and the '184 patent are owned and have always been owned by two separate entities. The Appellants' application is the earlier filed of the two by nearly four years. Thus, there would be no timewise extension of patent term as the present application, if granted, would expire years before the '184 patent.

MPEP Section 804 indicates that:

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity of the term of the patent. The public policy behind this doctrine is that:

The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent, but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.

MPEP (Rev. 5, Aug. 2006), Section 804, page 800-11.

As further noted in the discussion that follows, "double patenting exists when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982)." *Id.* As

pointed out above, in the present case, the extension of patent term is not an issue. The present application has an effective filing date of August 12, 1997 and if issued into a patent would expire August 13, 2017, well before the expiration date of the '184 patent.

The prohibition against the unjust extension of patent term is further reiterated in Section 804 of the MPEP, page 800-21, which sets forth that a nonstatutory double patenting rejection "is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

The present application has an effective filing date that is earlier than the filing date of the '184 patent. The priority date for the present application is August 12, 1997, whereas the priority date for the '184 patent is July 31, 2000. Based on the filing dates, the issuance of a patent in the present case will not extend patent term. In fact, a patent issuing from the present application will expire before the '184 patent. Accordingly, there is no patent term extension.

In response to Appellants' argument in the August 28, 2007 Response that the present application will not have a term that extends beyond the term of the '184 patent, the Advisory Action mailed September 18, 2007 states that a further rationale for requiring a terminal disclaimer is the concern of possible harassment by multiple assignees. The United States Court of Customs and Appeals in *In re Van Ornum* confirmed that this was a further rationale for requiring a terminal disclaimer and the tying together of the ownership (non-alienation) of two patents (686 F.2d 937, 948, 214 U.S.P.Q 761, 770 (CCPA 1982)).

Whenever the courts have discussed the concern of harassment by multiple assignees it has always been in terms of commonly owned patents that might subsequently be assigned or transferred to different parties. The court addressed this common ownership in *In re Van Ornum*, where it stated that "[t]his provision would prevent harassment of an alleged infringer by multiple parties due to subsequent different ownership of multiple patents granted as the result of filing a terminal disclaimer to overcome a double patenting rejection" (686 F.2d at

945, 214 U.S.P.Q at 768; emphasis added). In *Chisom on Patents*, a discussion of the issue of harassment by multiple assignees states that "[e]ven though both patents are issued to the same patentee or assignee, it is possible that ownership of the two would be divided by later transfer and assignments" (*Chisom on Patents*, Donald S. Chisom, Chapter 9, section 9.04[2][b][ii]; emphasis added). Since a terminal disclaimer can only be filed where the patents or applications are commonly owned, the requirement that a terminal disclaimer include a non-alienation clause dictates that there is common ownership.

There Is No Double Patenting Issue for the Present Application in View of the '184 Patent.

The section of the MPEP that governs the present situation is MPEP 804.03 IV, pages 800-37 through 800-39, regarding rejections under 35 USC § 102 and § 103 and double patenting. Form paragraph 7.21.01 *Provisional Rejection, 35 USC 103(a), Common Assignee or at Least One Common Inventor* should be applied to the present situation. The present application and the '184 patent do not have a common assignee or are not subject to a joint research agreement as defined by The CREATE Act. The present application and the '184 patent do share a common inventor.

MPEP form paragraph 7.21.01 indicates that in the present case the claims of the '184 patent should have been provisionally rejected under 35 USC § 103(a) as obvious over the present application, which was copending during the prosecution of the '184 patent. As stated in the form paragraph, "[b]ased upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. § 102(e) if published or patented. This provisional rejection under 35 U.S.C. § 103(a) is based upon a presumption of future publication or patenting of the conflicting application." MPEP, page 800-38.

As noted in the discussion that follows, this form paragraph should be used by an examiner to provisionally reject claims not patentably distinct from the disclosure in a copending application having an earlier U.S. filing date and also having either a common assignee or at least one common inventor. As noted on page 800-39, "if an application has a later effective U.S. filing date than a conflicting issued patent, the examiner should consider making a rejection in the application, based on the patent, under 35 U.S.C. § 102(e) or §§ 102(e)/103(a) using form paragraph 7.15.02 or 7.21.02." The discussion distinguishes the

present situation from the situation where the application and the patent are subject to a joint research agreement under The CREATE Act.

The fact overlooked by the Examiner in the present application is the fact that the **present application has an effective filing date that is earlier** than the filing date of the '184 patent. The priority date for the present application is August 12, 1997, whereas the priority date for the '184 patent is July 31, 2000. Thus, the '184 patent is not prior art for purposes of double patenting under 35 U.S.C. § 102 or § 103. The present application is the earlier filed application. Further, the present product claims were filed with the originally filed U.S. application in 1998 (U.S. Patent Application No. 09/132536) and were pending at the time the application that matured into the '184 patent was under prosecution. Thus, the proper rejection that could have been made by the examiner was to reject the application that matured into the '184 patent application over the present application. Appellants note that the application that matured into the '184 patent was determined by the USPTO to be both novel and non-obvious over the prior art including the PCT counterpart of the present application (PCT/US98/16683; WO 99/07210), which was specifically considered during this patentability evaluation.

In conclusion, based upon the procedures set forth in the MPEP based upon current patent law there is no double patenting issue for the present application in view of the '184 patent. Accordingly, the double patenting rejection should be withdrawn.

The CREATE Act Safe-Harbor Provisions Do Not Apply to the Present Application

As noted above, the present application and the '184 patent are not commonly assigned, nor subject to a joint research agreement, as provided by The CREATE Act. Thus, the double patenting concerns brought about by the CREATE Act are not an issue in the present application. The CREATE Act provides a simple means of extending the "safe harbor" provisions of current law that treats inventions of a common owner similarly to inventions made by a single person. To promote collaborative research within organizations, Congress enacted the Patent Law Amendments of 1984, which, inter alia, exempt "common owner" inventors from the application of certain types of prior art and information in obviousness determinations, subject to the exercise of the same double patenting principles that apply when inventions are made by a single inventor. Importantly, "[p]atents issued under this Act shall be enforceable in the same manner, to the same extent, and for the same

term as when patents are issued to a common owner or are subject to common assignment. The doctrine of 'obviousness-type double patenting,' a judicial doctrine used by courts to prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent's right to exclude, shall apply to such patent." H.R. REP. 108-425, page 5.

As set forth in Department of Commerce RIN 0651-AB76:

Once an examiner has established a *prima facie* case of obviousness under 35 U.S.C. § 103(a), the burden is on the Appellant to overcome the rejection by invoking 35 U.S.C. § 103(c) as amended by the CREATE Act. . . To overcome such a rejection via the CREATE Act, the Appellant must provide a statement in compliance with § 1.104(c)(4) to the effect that the prior art and the claimed invention were made by or on the behalf of parties to a joint research agreement, within the meaning of 35 U.S.C. § 103(c)(3), which was in effect on or before the date the claimed invention was made, and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. . . If the Appellant disqualifies the subject matter relied upon by the examiner in accordance with the CREATE Act and the procedures set forth in this final rule, the examiner will treat the application under examination and the 35 U.S.C. § 102(e), (f), or (g) prior art as if they are commonly owned for purposes of 35 U.S.C. § 103.

Federal Register Vol. 70, No. 177, 54259, 54261.

Thus, parties who seek to benefit from the CREATE Act waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection. A double patenting rejection is authorized where an Appellant invokes the new provisions of 35 U.S.C. § 103(c), even though there is neither a common inventor nor a common patent owner. Rule 1.109(b).

As discussed in the MPEP and in the CREATE Act, double patenting rejections may arise as a result of the amendment to 35 U.S.C. § 103(c) by the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). Congress recognized that this amendment to 35 U.S.C. § 103(c) would result in situations in which there would be double patenting rejections between applications not owned by the same party (see, H.R. Rep No. 108-425, at 5,6 (2003)). For purposes of double patenting analysis, the application or patent and the subject matter disqualified under 35 U.S.C. § 103(c) as amended by the CREATE Act will be treated as if commonly owned.

Congress recognized that this amendment to 35 U.S.C. § 103(c) would result in situations in which there would be double patenting between applications not owned by the same party. See H.R. Rep. No. 108-425, at 5-6

(2003). Therefore, the Office is providing the following guidelines for double patenting rejections based upon a patent or application that is not commonly owned but was disqualified under 35 U.S.C. § 103(c) as resulting from activities undertaken within the scope of a joint research agreement, which will be incorporated into the next revision of the MPEP.

Federal Register Vol. 70, No. 177, 54259, 54261.

However, this new category of double patenting created by the CREATE Act does not apply to the present application. Appellants are not seeking to benefit from the provisions provided by the CREATE Act. Furthermore, Appellants cannot take advantage of the provisions of the CREATE Act since there was no joint research agreement in place between the assignee of the present application and the assignee of the '184 patent at the time of invention of the present application. Accordingly, double-patenting under the CREATE Act does not apply to the present application and the rejection should be withdrawn.

Appellants further note that the MPEP section addressing the requirements of a double patenting rejection states that an "[o]bviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a *commonly owned patent*, or a *non-commonly owned patent but subject to a joint research agreement* as set forth in 35 U.S.C. 103(c)(2) and (3), when the issuance of a second patent would provide *unjustified extension of the term* of the right to exclude granted by a patent." MPEP § 804(II)(B)(1) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001) and *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000)) (emphasis added). The present application and the '184 patent are not commonly owned, nor are they subject to a joint research agreement. Further, there is no unjustified extension of term in this case (the term of protection for the present application will expire at least 3 years prior to that of the '184 patent). Thus, the fundamental purpose for which the judicially created doctrine of obviousness-type double patenting was intended, i.e., to prevent the unjustified extension of the term of the right to exclude granted by a patent (which purpose is repeated throughout the MPEP), is not present in this case (*See*, MPEP § 804, § 804 (II), § 804(II)(B) and § 804(II)(B)(1)).

Additionally, the MPEP states:

If the provisions of 35 U.S.C. § 103(c)(1) apply to the commonly owned conflicting inventions of different inventive entities or if the provisions of 35 U.S.C. § 103(c)(2) apply to non-commonly owned inventions subject to a joint research agreement and thereby obviate the obviousness rejection(s),

double patenting rejection(s) should be made (or maintained) as appropriate. **If, however, it is determined that the provisions of 35 U.S.C. § 103(c) do NOT apply** because the inventions were not commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, or because the claimed invention did NOT result from activities undertaken within the scope of a joint research agreement as required by 35 U.S.C. § 103(c)(2) and (3), **and** there is evidence of record to indicate that a patent or application is prior art against the application being examined, the examiner should make (A) any appropriate double patenting rejection(s), and (B) the appropriate prior art rejection(s) under 35 U.S.C. § 102 and/or 35 U.S.C. § 103 in the application being examined.

MPEP § 804.03(IV) (emphasis added). Again, none of these fact patterns identified as appropriate for a double patenting rejection are found in the instant case. The provisions of §103(c) do not apply and the '184 patent is not prior art against the present application.

The same scenarios that are discussed in MPEP § 804.03(IV) (discussed in the preceding paragraph) are presented in Chart IIB in § 804 of the MPEP (marked copy enclosed herewith in the Evidence Appendix). Chart IIB is a flow chart providing an outline of the treatment of applications with conflicting claims. If one follows the path for "different inventive entities, at least one common inventor and no common assignee" (middle of the chart) and then follows the path for "no joint research agreement" (all of which are the circumstances of the present application), this chart shows that a double patenting rejection is appropriate when the reference application or patent is prior art against the patent application at issue. It is specifically noted in Chart IIB that the term "**AND**" is used between the different rejections to be made. The use of "AND" is clearly intentional as "AND/OR" is used in another section of Chart IIB (see the path for "currently commonly owned→different inventive entities"). Thus, the drafters of this section of the MPEP clearly understood the difference and deliberately chose to use "AND" under the particular circumstances where the application and the application/patent have different inventive entities, at least one common inventor, no common assignee, and no joint research agreement. As stated previously, since the '184 patent does not qualify as prior art against the present application, these rejections as outlined in Chart IIB cannot be made. Thus, Appellants respectfully submit that the requirements for a proper double patenting rejection as set forth in the MPEP are not met in this case, and therefore, the present double patenting rejection is improper.

Even if a Double Patenting Rejection were Proper, the Appropriate Test is the Two-Way Obviousness Test.

Appellants submit that should a double patenting rejection be determined to be proper, then the appropriate test in the circumstances of the present application is a two-way obviousness test. In considering the issue of non-statutory obviousness-type double patenting the MPEP states that a "[i]f the patent is the later filed application, the question of whether the timewise extension of the right to exclude granted by a patent is justified or unjustified must be addressed. A two-way test is to be applied only when the applicant could not have filed the claims in a single application *and* there is administrative delay." MPEP, § 804(II)(B)(1)(b).

Furthermore, In *In re Bratt* (937 F.2d 589, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991)), the Court of Appeals for the Federal Circuit agreed with "...the proposition that when a later filed improvement patent issues before an earlier filed basic invention, a double patenting rejection is only proper against the claims to the basic invention if the improvement is not patentably distinct from the basic invention. The rationale behind this proposition is that an Appellant (or Appellants), who files applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the Appellant does not have complete control." (937 F.2d at 593, 19 U.S.P.Q.2d at 1292; emphasis added). In *In re Bratt*, the court found that not only could the claims of the later filed application not have been included in the earlier filed application but that the Appellant did not have complete control over the progress of the applications through the PTO. (937 F.2d at 593-4, 19 U.S.P.Q.2d at 1292).

In the present case, the improvement in the later filed application that matured into the '184 patent could not have been presented in the present application as the '184 application claims an invention not disclosed in the present application. (See, *In re Berg* 140 F.3d 1428, 1438; 46 U.S.P.Q.2d 1226, 1233 (1998)). Secondly, the second filed invention (that matured into the '184 patent) was not conceived until after the present application was filed (2001 and 1997, respectively). Lastly, the applications are owned a prosecuted by different assignees.

In addition, the Appellants did not have control over the rate of progress of both applications through the PTO. The Appellants have diligently prosecuted the family of applications from which the present application is derived. Appellants did not file the '184 application as it is owned by an entirely different entity. Thus, Appellants not only did not

have any control over when (or if) the second application was filed, they had no control over its prosecution.

It is unfair to penalize an entity with an earlier filed application by allowing a second file application of completely different entity to block the first filed application simply because the first entity employed an inventor who decided to pursue a career with the second entity and then invented improvements to the first entity's invention. This is clearly something that is out of the control of the first entity. The present case represents just this circumstance when an inventor leaves the auspices of a prior employer to be employed by another company, often a competitor. The only connection these inventions have is a single inventor. Thus, Appellants had no control over the filing and prosecution of the second filed application.

As it stands, the USPTO's position on the present double patenting rejection achieves absurd results. Since the application and patent at issue were filed as two separate inventions under the auspices of two separate entities, a terminal disclaimer cannot be filed to overcome the rejection. Thus, in this case, the senior party would appear to be blocked from obtaining a patent by a junior party. If this rejection is maintained, the only way to achieve any fairness is to apply the two way obviousness test. Accordingly, Appellants contend that if a double patenting rejection is found to be proper then the appropriate test for such a rejection is the two-way obviousness test.

Applying the two-way obviousness test requires application of the Graham obviousness analysis twice, once with the application claims as the claims in issue and once with the patent claims in issue. MPEP § 804(II)(B)(1)(b). If either analysis does not compel a conclusion of obviousness, no double patenting rejection of the obvious type is made. *Id.* Appellants note that the '184 patent was determined by the USPTO to be both novel and non-obvious over the prior art including the PCT counterpart of the present application (PCT/US98/16683; WO 99/07210), which was specifically considered during the patentability evaluation of the '184 patent. Thus, at least one of the required analyses under the two-way obviousness test does not compel a conclusion of obviousness and therefore, the double patenting rejection cannot be made.

For all of these reasons, the rejections of claims 11 and 32 on the ground of non-statutory obviousness-type double patenting over claim 1 of U.S. Patent No. 6,815,184 in view of Dieryck et al. should be reversed.

III. Claims 1-10, 12-31 and 33-40 are improperly rejected as unpatentable on the ground of non-statutory obviousness-type double patenting over claims 1 and 22-25 of U.S Patent Application No. 11/778,480.

The Advisory Action has withdrawn the rejection of claims 1-10, 12-31 and 33-40 as unpatentable on the ground of non-statutory obviousness-type double patenting over claims 1 and 22-25 of U.S Patent Application No. 10/873,846 (herein after "the '846 application") and has now rejected claims 1-10, 12-31 and 33-40 as unpatentable on the ground of non-statutory obviousness-type double patenting over claims 1 and 22-25 of U.S Patent Application No. 11/778,480 (hereinafter "the '480 application"), which is a continuation application of the '846 application. The '846 application is abandoned.

Since no claims have yet issued, this rejection is provisional. Thus, Appellants will address this rejection once claims are issued from the '480 application. Accordingly, should claims issue in the '480 application prior to the allowance of claims in the present application and a double patenting rejection is issued, Appellants will address such a rejection at that time. Thus, this rejection is believed to be adequately addressed and Appellants respectfully request its withdrawal.

IV. Claims 11 and 32 are improperly rejected as unpatentable on the ground of non-statutory obviousness-type double patenting over claim 1 of U.S Patent No. 6,815,184 in view of Dieryck et al. (Transfus. Clin. Biol. 2: 441-447 (1995)).


This rejection is repetitive of the rejection cited above in section II. Appellants believe that the rejection was originally intended to cite the '846 application. Accordingly, Appellants believe that similar to the above rejection discussed in section III (above) this rejection is also withdrawn. However, since this rejection was not addressed in the Advisory Action and was apparently incorrectly cited in each of the previous Office Actions (mailed on July 28, 2006 and February 28, 2007), it is not clear what the rejection should state.

However, if it was intended that the '480 application be cited, then similar to the rejection discussed above in section III, this is a provisional rejection because no claims have issued in the case of the '480 application. Accordingly, should claims issue in the '480 application prior to the allowance of claims in the present application and a double patenting rejection is issued, Appellants will address such a rejection at that time. Thus, this rejection is believed to be adequately addressed and Appellants respectfully request its withdrawal

V. Conclusion.

In light of the entire record and the above discussion, Appellants respectfully submit that claims 1-40 are patentable over U.S Patent No. 6,815,184 alone or in combination with Dieryck et al. and over U.S Patent Application No. 11/778,480 alone or in combination with Dieryck et al. Accordingly, Appellants respectfully request reversal of the pending rejection of claims 1-40 and that this case be passed to issuance.

Respectfully Submitted,



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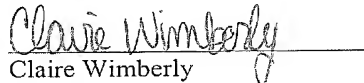

Claire Wimberly

TABLE OF AUTHORITIES

CASES

<i>In re Van Ornum</i> , 686 F.2d 937, 214 USPQ 761 (CCPA 1982).....	5, 6, 14, 15
<i>In re Goodman</i> , 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).....	5, 15
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OTHER REFERENCES

MPEP (Rev. 5, Aug. 2006), Section 804.....	5, 7-22
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CLAIMS APPENDIX

What is claimed is:

1. (Original) A stably transformed duckweed plant comprising a heterologous nucleic acid of interest incorporated in its genome.
2. (Original) The stably transformed duckweed plant according to Claim 1, wherein said duckweed plant comprises fewer than 5 copies of said heterologous nucleic acid of interest.
3. (Original) The stably transformed duckweed plant according to Claim 1, wherein said duckweed plant is selected from the group consisting of the genus *Spirodela*, genus *Wolffia*, genus *Wolffiella*, and genus *Lemna*.
4. (Original) The stably transformed duckweed plant according to Claim 3, wherein said duckweed plant is selected from the genus *Lemna*.
5. (Previously presented) The stably transformed duckweed plant according to Claim 4, wherein said duckweed plant is selected from the group consisting of *Lemna minor*, *Lemna miniscula*, and *Lemna gibba*.
6. (Previously presented) The stably transformed duckweed plant according to Claim 5, wherein said duckweed plant is *Lemna minor*.
7. (Original) The stably transformed duckweed plant according to Claim 1, wherein said nucleic acid comprises at least one expression cassette comprising a gene which confers resistance to a selection agent.
8. (Original) The stably transformed duckweed plant according to Claim 7, wherein said gene which confers resistance to a selection agent is selected from the group consisting of *neo*, *bar*, *pat*, *ALS*, *HPH*, *HYG*, *EPSP* and *Hml*.

9. (Original) The stably transformed duckweed plant according to Claim 1, wherein said nucleic acid comprises two genes of interest.

10. (Original) The stably transformed duckweed plant according to Claim 1, wherein said nucleic acid encodes a protein or peptide selected from the group consisting of insulin, growth hormone, α -interferon, β -glucocerebrosidase, retinoblastoma protein, p53 protein, angiostatin, leptin, and serum albumin.

11. (Original) The stably transformed duckweed plant according to Claim 1, wherein said nucleic acid encodes at least one protein or peptide subunit of a multimeric protein selected from the group consisting of hemoglobin, collagen, P450 oxidase, and a monoclonal antibody.

12. (Original) The stably transformed duckweed plant according to Claim 1, wherein said nucleic acid encodes a secreted protein or peptide.

13. (Original) A stably transformed duckweed plant tissue comprising a heterologous nucleic acid of interest incorporated in its genome.

14. (Original) The stably transformed duckweed plant tissue according to Claim 13, wherein said plant tissue is meristematic tissue.

15. (Original) The stably transformed duckweed plant tissue according to Claim 13, wherein said plant tissue is frond tissue.

16. (Original) The stably transformed duckweed plant tissue according to Claim 13, wherein said plant tissue is callus tissue.

17. (Original) The stably transformed duckweed plant tissue according to Claim 16, wherein said plant tissue is Type I callus tissue.

18. (Original) A duckweed tissue culture comprising the stably transformed duckweed plant tissue of Claim 13.

19. (Original) A stably transformed duckweed cell comprising a heterologous nucleic acid of interest incorporated in its genome.

20. (Original) A stably transformed duckweed plant comprising a chimeric nucleic acid of interest incorporated in its genome, wherein said chimeric nucleic acid comprises a coding sequence operably linked to a transcription initiation region that is heterologous to said coding sequence.

21. (Original) The stably transformed duckweed plant according to Claim 20, wherein said chimeric nucleic acid comprises a duckweed coding sequence operably linked to a transcription initiation region that is heterologous to said coding sequence.

22. (Original) The stably transformed duckweed plant accordingly to Claim 20, wherein said chimeric nucleic acid is flanked by T-DNA border sequences.

23. (Original) The stably transformed duckweed plant according to Claim 20, wherein said duckweed plant comprises fewer than 5 copies of said chimeric nucleic acid.

24. (Original) The stably transformed duckweed plant according to Claim 20, wherein said duckweed plant is selected from the group consisting of the genus *Spirodela*, genus *Wolffia*, genus *Wolffiella*, and genus *Lemna*.

25. (Original) The stably transformed duckweed plant according to Claim 24, wherein said duckweed plant is selected from the genus *Lemna*.

26. (Previously presented) The stably transformed duckweed plant according to Claim 25, wherein said duckweed plant is selected from the group consisting of *Lemna minor*, *Lemna miniscula*, and *Lemna gibba*.

27. (Previously presented) The stably transformed duckweed plant according to Claim 26, wherein said duckweed plant is *Lemna minor*.

28. (Original) The stably transformed duckweed plant according to Claim 20, wherein said chimeric nucleic acid of interest comprises at least one expression cassette comprising a gene which confers resistance to a selection agent.

29. (Original) The stably transformed duckweed plant according to Claim 28, wherein said gene which confers resistance to a selection agent is selected from the group consisting of *neo*, *bar*, *pat*, *ALS*, *HPH*, *HYG*, *EPSP* and *Hml*.

30. (Original) The stably transformed duckweed plant according to Claim 20, wherein said chimeric nucleic acid comprises two genes of interest.

31. (Original) The stably transformed duckweed plant according to Claim 20, wherein said chimeric nucleic acid encodes a protein or peptide selected from the group consisting of insulin, growth hormone, α -interferon, β -glucocerebrosidase, retinoblastoma protein, p53 protein, angiostatin, leptin, and serum albumin.

32. (Original) The stably transformed duckweed plant according to Claim 20, wherein said chimeric nucleic acid encodes at least one protein or peptide subunit of a multimeric protein selected from the group consisting of hemoglobin, collagen, P450 oxidase, and a monoclonal antibody.

33. (Original) The stably transformed duckweed plant according to Claim 20, wherein said chimeric nucleic acid encodes a secreted protein or peptide.

34. (Original) A stably transformed duckweed plant tissue comprising a chimeric nucleic acid of interest incorporated in its genome, wherein said chimeric nucleic acid comprises a coding sequence operably linked to a transcription initiation region that is heterologous to said coding sequence.

35. (Original) The stably transformed duckweed plant tissue according to Claim 34, wherein said plant tissue is meristematic tissue.

36. (Original) The stably transformed duckweed plant tissue according to Claim 34, wherein said plant tissue is frond tissue.

37. (Original) The stably transformed duckweed plant tissue according to Claim 34, wherein said plant tissue is callus tissue.

38. (Original) The stably transformed duckweed plant tissue according to Claim 37, wherein said plant tissue is Type I callus tissue.

39. (Original) A duckweed tissue culture comprising the stably transformed duckweed plant tissue of Claim 34.

40. (Original) A stably transformed duckweed cell comprising a chimeric nucleic acid of interest incorporated in its genome, wherein said chimeric nucleic acid comprises a coding sequence operably linked to a transcription initiation region that is heterologous to said coding sequence.

EVIDENCE APPENDIX

1. Chart IIB in § 804 of the MPEP (marked copy) provided to the Examiner in the response submitted on August 28, 2007.

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RELATED PROCEEDINGS APPENDIX

(none)